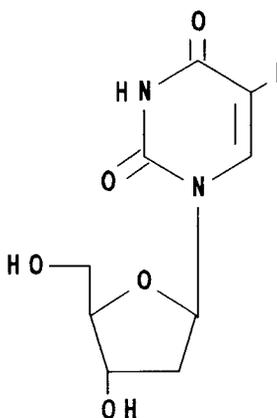


IODODEOXYURIDINE

NSC - 39661

The following information applies to the investigational dosage form of iododeoxyuridine. For information on the commercially available dosage form, consult the package insert supplied by the manufacturer.



Chemical Name: 5-Iodo-2'-deoxyuridine

Other Names: IDU, IUdR, IdUrd, Idoxuridine (USAN)

CAS Registry Number: 54-42-2

Molecular Formula: $C_9H_{11}IN_2O_5$

M.W.: 354.1

How Supplied: Sterile, 200 mg, vial: supplied as a white lyophilized powder with sodium hydroxide to adjust pH in 30 mL amber vials.

Solution Preparation: 200 mg/vial: When constituted with 10 mL of Sterile Water for Injection, USP, each milliliter contains iododeoxyuridine 20 mg with sodium hydroxide to adjust to pH 9 to 10.

Storage: Store the intact vials at room temperature.

Stability: Intact vials are stable for five years when stored at room temperature and are stable for at least one year when stored at elevated temperatures (50 °C).

At a concentration of 20 mg/mL in distilled water, iododeoxyuridine is stable exhibiting less than 2% decomposition in 2 days at room temperature (22-25 °C). Particulate matter was observed in the solution after 2 days.

Diluted to a concentration of 0.5 mg/mL in 5% Dextrose Injection, USP, or 0.9% Sodium Chloride Injection, USP, iododeoxyuridine is also stable, exhibiting less than 4% decomposition in 14 days at room temperature (22-25 °C).

CAUTION: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous